Complementary and alternative exercise for fibromyalgia: a meta-analysis

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Abstract: Complementary and alternative medicine includes a number of exercise modalities, such as tai chi, qigong, yoga, and a variety of lesser-known movement therapies. A meta-analysis of the current literature was conducted estimating the effect size of the different modalities, study quality and bias, and adverse events. The level of research has been moderately weak to date, but most studies report a medium-to-high effect size in pain reduction. Given the lack of adverse events, there is little risk in recommending these modalities as a critical component in a multimodal treatment plan, which is often required for fibromyalgia management.

Keywords: fibromyalgia, exercise, complementary and alternative, efficacy, safety

Introduction
Fibromyalgia (FM) is a debilitating chronic pain condition affecting ∼15 million persons in the USA and is one of the more severe disorders on the continuum of persistent pain.1–4 FM results in profound suffering, including widespread musculoskeletal pain and stiffness, fatigue, disturbed sleep, dyscognition, affective distress, and very poor quality of life.5,6 Among FM patients, 20%–50% work few or no days despite being in their peak wage-earning years.6,7 Disability payments are received by 26%–55% of FM patients compared with the national average of 2% of patients who receive disability payments from other causes.7–9 Furthermore, health care costs are three times higher among FM patients compared with matched controls.9

Diminished aerobic fitness in FM has been documented for almost three decades, and recent studies report that the average 40-year-old with FM has fitness findings expected for a healthy 70 to 80-year-old, and FM has now also been associated with increased mortality.2,3,11–14 Tailoring exercise to patients with FM requires an understanding of the relevant pathophysiology. FM is likely due in part to altered pain processing in the central and peripheral nervous system.15–17 Additional pathophysiologic factors include genetic predispositions, autonomic dysfunction, and emotional, physical, or environmental stressors.18 Neurohormonal and inflammatory dysfunctions are implicated in muscle microtrauma and ischemia, a potent pain generator during and after exercise.15,18–24 The majority of persons with FM have four or more comorbid pain or central sensitivity disorders, including irritable bowel/bladder, headaches, pelvic pain, regional musculoskeletal pain syndromes (such as low back pain), chronic fatigue, and restless leg syndromes, suggesting shared pain processing in these common comorbidities.25–27 Multiple symptoms and poor physical function are underpinned by physiologic abnormalities found in FM and other chronic pain conditions.
Drug therapies for FM offer some help, improving pain by ~30% and function by ~20%. Drug access and costs are challenging, however, as none are available in generic formulation. Further, they carry safety concerns and may produce side effects, such as nausea, edema, weight gain, or tachycardia.\textsuperscript{27–31} Unfortunately, no new FM drugs are in Phase III testing or under Food and Drug Administration (FDA) review, shifting the urgency to the development of novel, safe, effective nonpharmacological strategies, including exercise.\textsuperscript{32}

Based on results of over 100 studies, exercise has been strongly recommended as an adjunct to drug therapy for FM.\textsuperscript{33–36} Of these studies, approximately 80% are aerobic or mixed-type (aerobic, strength, flexibility).\textsuperscript{37–44} New data have emerged since these key position statements were published. Namely, a meta-analysis of studies with low attrition concluded that immediately postintervention, high quality aerobic or mixed modality exercise reliably restored physical function or fitness (d = 0.65) and health-related quality of life (d = −0.40), while exerting no significant effects on sleep (d = 0.01). Effect sizes for pain were small (d = −0.31) and not sustained at follow up (d = 0.13).\textsuperscript{41} Similarly, 14 strength or stretching studies consistently demonstrated improvements in fatigue and physical function but inconsistently improved other FM symptoms.\textsuperscript{39,42} Studies included in the meta-analysis had a median attrition of 67% (range 27%–90%), suggesting that the interventions themselves were not acceptable. Some early programs dosed the intervention too high (exercise frequency, intensity, and timing) or required medication washout, leading to an attrition rate averaging approximately 40%. Others selected inappropriate exercise modalities, such as running, fast dancing, or high-intensity aerobics, resulting in 62%–67% attrition.\textsuperscript{45,46}

In search of more comprehensive and continued symptom relief, FM patients have been increasingly adopting complementary and alternative exercise therapies, such as qigong, tai chi, yoga, and a variety of lesser-known movement therapies.\textsuperscript{47,48} Qigong and tai chi both have origins in the Chinese martial arts. They involve physical movement integrated with mental focus and deep breathing. They seek to cultivate and balance qi (chi), which is sometimes translated as “intrinsic life energy.” Yoga is “a union of mind and body” with origins in ancient Indian philosophy. In yoga, physical postures (“asanas”) are generally practiced in tandem with breathing techniques (“pranayama”) and meditation or relaxation.

Langhorst et al\textsuperscript{39} recently published a meta-analysis of randomized controlled trials (RCTs) on meditative movement in FM, concluding that these modalities were safe and effective for selected FM symptoms. The aim of this paper is to extend Langhorst’s work by providing a comprehensive review of a broader array of land-based complementary and alternative medicine (CAM) FM exercise studies, including early-stage research. For the purposes of this review, exercise is defined as planned, structured physical activity whose goal is to improve one or more of the major components of fitness – aerobic capacity, strength, flexibility, or balance. CAM is defined as “a group of diverse medical and health care systems, practices, and products that are not generally considered to be part of conventional medicine.”\textsuperscript{50}

**Material and methods**

**Literature search strategy**

Electronic databases were screened during October 2012, including SciVerse Scopus, Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed/Medline, Cochrane Library, and PsyhiInfo. The key medical subject heading (MeSH) terms for initial inclusion were “fibromyalgia” and “fibromyalgia syndrome” combined with “yoga,” “tai chi,” “pilates,” “taiji,” and “qigong.” To maximize the search results, no search limitations of language, year, or study design were implemented. Additional studies were identified through the bibliographies of selected studies and personal contact with researchers in the field.

**Selection criteria**

To determine their initial eligibility, all potential studies were retrieved in full text and reviewed for the inclusion criteria. All three authors independently screened all identified full-text articles, to determine whether the study met the inclusion criteria. To be included in this review, studies had to meet the following criteria: (1) enrollment of participants 21 years of age and older who met the standardized criteria for FM diagnosis, (2) study intervention met the definitions for CAM and land-based exercise, and (3) inclusion and reporting of pre- and post-Fibromyalgia Impact Questionnaire (FIQ) total score or numeric pain rating scale scores.\textsuperscript{51,52} This means that CAM studies with very low levels of exertion, such as studies of body awareness therapies, breathing studies, and mindfulness-based stress reduction (which generally offers very brief yoga in two out of eight sessions), were not included. Additionally, we excluded water-based CAM therapies, such as tai chi in water and yoga/breathing in water, as it is unclear whether the benefit derived from balneotherapeutic effects or physical movement and mindful techniques (Figure 1).\textsuperscript{53,54}
Data extraction
All review authors participated in data extraction. Data were extracted in the following content areas: study design, type of CAM exercise, sample size, subject characteristics (age and gender), treatment duration, frequency and dose, adherence to treatment, attrition rates, and outcome variables and results. Any discrepancies between authors were discussed and consensus obtained. When studies did not include enough information to calculate the effect size estimates on pain, the authors were contacted to request the data required for a complete statistical analysis. Most of these reported point estimates rather than effect sizes. All studies for which effect sizes could not be calculated, were excluded from this review.

Statistical analysis
The analysis was completed using Comprehensive Meta Analysis software, Version 2.2.064 (Biostat Inc., Englewood, NJ, USA). Standard formulas were used to calculate standardized mean differences and standard errors. Overall estimates of treatment effect used a random effects meta-analysis. Subgroup analyses were conducted with respect to treatment modality. A common among-study variance component across subgroups was not used when calculating the effect size of the individual modalities.

Quality assessment
The methodological quality of the selected studies was assessed using the Jadad score, assessing for randomization, blinding, and clear explanations for study dropouts. While Jadad scoring is intended for RCTs, the authors thought that it was a good, if simple, measure of methodological quality, allowing nonrandomized trials in this review the possibility of a score of 0 or 1 and RCTs a maximum score of 3. Normally the Jadad score has a range of 0 to 5, but as it is not possible to blind the interventionist to the treatment in CAM exercise, the maximum achievable score is 3. The average score for the studies in this review was 1.7 (range 1 to 3).

Sensitivity and validity analysis
A funnel plot was constructed of standard differences (Std diff) in means by standard errors, with two standard deviations displayed. A random distribution of studies indicated a low publication bias. A regression of the Jadad score on the Std diff in means was calculated. The slope is indicative of publication bias by quality of study. A slope of zero indicates that there was no bias.

Results
Study design
As the field has a relatively low number of reported RCTs, we included time-series trials. Due to this limitation, the relative study strength was moderately low. Time-series trials were adjusted for the relative overestimation of strength. However, one can see that the time series still represented some of the largest reported effects. Table 1 reports the details of each study.

Participants
A total of 832 FM patients participated in the reviewed studies, with 490 allocated to the CAM exercise interventions. The median of the sample size for the CAM exercise interventions was 23 (range 6–64). The median percentage of patients completing the study was 81%, and there was no significant difference in dropout among those studies that included a comparison arm. In all of the studies, the FM diagnosis was made in accordance with the American College of Rheumatology 1990 criteria.

Outcomes
In all studies, except for one by Curtis et al, the FIQ total score or FIQ Pain Score was used as the primary outcome. The Curtis et al study used the McGill Pain Questionnaire, and in this case, the total McGill Pain Questionnaire was...
Table 1 Summary of included trials

<table>
<thead>
<tr>
<th>Author</th>
<th>Study type/design</th>
<th>Intervention and dose</th>
<th>Sample size, age and adverse events</th>
<th>Post intervention follow up</th>
<th>Outcome measures and timing</th>
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<tbody>
<tr>
<td><strong>Qigong studies</strong></td>
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<tr>
<td>Lynch, Sawynok, Hiew, and Marcon (2012)</td>
<td>Randomized controlled trial (RCT)</td>
<td>Qigong Intervention = three 1/2 day workshop followed by weekly review/practice sessions over 8 weeks in addition 45–60 minutes of home practice per day Control = wait list control</td>
<td>n = 100 Immediate intervention n = 53 Wait list control n = 47 Mean age = 52 years Immediate qigong completion rate = 83.01% at 2 months Wait-list qigong completion rate = 95.7% at 2 months</td>
<td>4 and 6 month follow-up</td>
<td>Pain (numeric rating scale) Fibromyalgia Impact Questionnaire (FIQ) Pittsburgh Sleep Quality Index (PSQI) SF-36 health survey</td>
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<tr>
<td>Liu, Zahner, Cornell, Le, Rater, Wang, Pasnoor, Dimachkie and Barohn (2012)</td>
<td>Single blinded</td>
<td>Qigong Intervention = home practice for 15–20 minutes twice daily and group exercise class for 45–60 minutes once daily for 6 weeks Control = home practice for 15–20 minutes twice daily and group exercise class for 45–60 minutes once weekly using “sham” qigong moves for 6 weeks</td>
<td>n = 14 Intervention group n = 8 Mean age = 55.7 years Control group n = 6 Mean age = 57.5 years Total completion rate = 85.7% Intervention group completion rate = 75% Control group completion rate = 100% Adverse events = not addressed</td>
<td>No follow up</td>
<td>Pre/post only Short Form McGill Pain Questionnaire (SF-MPQ) Multidimensional Fatigue Inventory (MFI-20) PSQI FIQ</td>
</tr>
<tr>
<td>Haak and Scott (2008)</td>
<td>RCT</td>
<td>Qigong 7-week qigong intervention consisting of 9 group sessions and approx. 11.5 hours total dose Home practice encouraged 2x/day</td>
<td>n = 57 women Intervention n = 29 Wait list Control n = 28 Mean age = 53 years Total completion rate n = 53 (93%) Adverse events = not addressed</td>
<td>4 month follow up</td>
<td>Pre/post/4 month follow up State Anxiety Inventory (STAI) Beck Depression Inventory (BDI) World Health Organization Quality of Life BREF (WHOQOL-BREF) Daily self-recordings visual numerical scale (VNS) on pain, sleep, psychological health and distress</td>
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<tr>
<td>Mannerkorpi and Arndorw (2004)</td>
<td>RCT Pre/post test</td>
<td>Qigong 14 sessions over 3 month period, once weekly for 1.5 hours Home practice encouraged Data unclear regarding dose of home practice performed</td>
<td>n = 36 women Mean age = 45 years Adverse events = none reported</td>
<td>No follow up</td>
<td>FIQ Body Awareness Rating Scale (BARS) Chair test hand grip Interviews</td>
</tr>
</tbody>
</table>

Comments: *This is 1 of only 2 studies with 6-month follow-up; only study identified using chaoyi fanhaun qigong (CFQ). Comment: 1st study to test and report sham qigong arm. Comments: Use of he hua qigong style, only study done outside the United States. Comments: Differential attention between groups as standard care control didn’t meet in groups or receive attention from Primary Investigator (PI) other than at data collection points; significant change in body awareness and FIQ but not in measures of physical function; only qigong study with a negative outcome despite standard care group receiving no attention; 8 participants reported increased pain with qigong practice.
Mindfulness meditation plus qigong
2.5 hour weekly sessions of mind-body intervention over 8 weeks
1.5 hr mindfulness meditation training and 1 hr qigong practice over 8 weeks
Control group 2.5 hour educational sessions for 8 weeks

n = 128 individuals
Mean age = 47.7 years
8 week attrition = 39% (50)
16 week attrition = 48% (61)
24 week attrition = 49% (63)
25.8% never attended even one class
18.8% qigong; 32.8% control
Adverse events = not addressed

4 and 6 month follow up
Baseline, 8, 16, and 24 weeks
Tender point count
Total myalgic score
Medical Outcome Study Short Form
FIQ
6 minute walk test;
BDI
Medical care history
Coping strategies questionnaire

59 RCT

Comments: 1st study to report qigong intervention in fibromyalgia; largest study to date; 1 of 2 studies with 6 month follow up; equal attention paid to the sedentary control group; only study to use the ‘dance of the phoenix’ qigong style.

Yoga studies


Hatha yoga with mindfulness technique
Twice weekly, 75 minute yoga classes per week over 8 weeks

n = 22
Completion rate = 86.36%
Mean age = 47.4 years
Adverse events = not addressed

No follow up
Pre/mid/post measures
SF-MPQ
Pain numeric rating scale
Sum of Local Areas of Pain (SLAP)
Pain Catastrophizing Scale (PCS)
Pain Disability Index (PDI)
Hospital Anxiety and Depression Scale (HADS)
Five Facet Mindfulness Questionnaire (FFMQ)
Chronic Pain Acceptance Questionnaire (CPAQ)
Salivary cortisol measurement

67 Time series design

Carson, Carson, Jones, Mist and Bennett (2010)41

Yoga with mindfulness
120 minute sessions, once weekly over 8 weeks
Participants encouraged to practice at home 20–40 min/day 5–7x/week with DVD/CD

n = 39 women
Immediate intervention n = 21
Wait list control n = 18
Immediate intervention group completion rate = 88%
3 month follow up rate = 84%
Wait list control group completion rate = 92.9%
3 month follow up
Adverse events = not addressed

Pre/post/3 month follow up
Revised FIQ (FIQR)
Patient global impression of change
Myalgic tender points
Strength deficits (timed chair rise)
Balance deficits (Sensory integration for balance test)
CPAQ
PCS
Coping strategies (Vanderbilt multidimensional pain coping inventory)
Daily diaries

Comments: 1st yoga study with group didactic discussion and presentation of mindfulness and yogic coping strategies; 2012 publication describes positive longer term follow up results.

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<table>
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<tr>
<th>Author</th>
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<tr>
<td>Romero-Zurita, Carbonell-Baeza, Aparicio, Ruiz, Torcedor and Delgado-Fernandez (2012)</td>
<td>Single group</td>
<td>8 form Yang style tai chi, 60 minute tai chi sessions, 3 times weekly over 7 months</td>
<td>n = 32 women</td>
<td>3 months post intervention</td>
<td>Pre/post/3 months post intervention             Tender points</td>
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<td>Completion rate = 73%</td>
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<td>Senior functional fitness test battery</td>
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<td>Adherence rate to intervention = 79.8%</td>
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<td>Handgrip strength</td>
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<td>Adverse events = none reported</td>
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<td>Blind flamingo</td>
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<td>8 form Yang style tai chi, 60 minute tai chi sessions, 3 times weekly over 7 months</td>
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<td>Chair stand test</td>
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<td>Chair sit and reach test</td>
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<td>Back scratch test</td>
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<td>8 feet up and go test</td>
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<td>6 minute walk test</td>
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<td>FIQ</td>
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<td>Short form health survey 36</td>
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<td>Vanderbilt Pain Management Inventory (VPMI)</td>
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<td>Rosenberg Self-Esteem Scale (RSES)</td>
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<td>General self-efficacy scale</td>
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<td>Comments: Longest tai chi study to date.</td>
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<td>Jones, Sherman, Mist, Carson, Bennett and Li (2012)</td>
<td>RCT</td>
<td>8 form Yang tai chi</td>
<td>n = 101 participants</td>
<td>No follow up</td>
<td>Pre/post measures</td>
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<td>90 min tai chi sessions, 2 times weekly for 12 weeks (simplification of an 8-form Yang style program)</td>
<td>Mean age = 54 years</td>
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<td>FIQ</td>
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<td>Educational session lasting 90 minutes, 2 times weekly</td>
<td>Completion rate = 97%</td>
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<td>FIQ Numeric Rating Scale (NRS) for pain severity</td>
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<td>At least 20/24 classes attended</td>
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<td>Brief Pain Inventory (BPI)</td>
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<td>by 72% of participants</td>
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<td>PSQI</td>
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<td>Adverse events = none reported</td>
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<td>Arthritis self-efficacy questionnaire</td>
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<td>Functional mobility 8-foot Timed Up and Go (TUG)</td>
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<td>Balance-maximum reach test</td>
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<td>Static balance-timed single leg stance (STORK)</td>
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<td>Upper extremity/flexibility-external and internal rotation of the shoulders by a hand to scapula movement</td>
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<td>Tenderness-algometer score</td>
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<td>Functional capacity - Height/Weight/Body Mass Index (BMI)</td>
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<td>Carbonnell-Baeza, Romero, Aparicio, Ortega, Torcedor, Delgado-Fernandez and Ruiz (2011)</td>
<td>Open label</td>
<td>8 form Yang style tai chi, 60 minute sessions, 3 times weekly for 16 weeks</td>
<td>27 contacted, 9 consented, 3 not included due to not meeting ACR diagnostic criteria</td>
<td>3 month post intervention follow-up</td>
<td>Lower body muscular strength-30 sec chair stand test</td>
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<td>Each session included: 15 min warm-up, 30 min of tai chi, 15 minutes of relaxation exercises</td>
<td>n = 6</td>
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<td>Upper body strength-handgrip strength</td>
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<td>Mean age = 52.3 years</td>
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<td>Lower body flexibility-chair sit and reach test</td>
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<td>Adherence = 79.5%</td>
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<td>Upper body flexibility- the back scratch test</td>
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<td>Adverse events = none reported</td>
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<td>Static balance- blind flamingo test</td>
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<td>Motor agility/dynamic balance- 8 feet up and go test</td>
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<td>Aerobic endurance- 6 minute walk test</td>
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<td>FIQ</td>
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<td>Short-form health survey (QOL)</td>
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<td>HADS</td>
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**Table 1 (Continued)**

Comments: A 4 month tai chi intervention improved lower body flexibility in men with fibromyalgia that persisted through a detraining period.
Wang, Schmid, Rones, Kalish, Yin, Goldenberg, Lee and McAlindon (2010)  
Single blind RCT  
10 form Yang style tai chi  
60 minute tai chi sessions twice weekly for 12 weeks  
Control: 60 minute wellness education and stretching program twice weekly for 12 weeks  
\( n = 66 \)  
Control \( n = 33 \)  
Intervention \( n = 33 \)  
Mean age: 50 years  
85% women  
12 week class completion rate: 92.4%  
24 week follow up completion rate: 89.4%  
Intervention adherence: 77%  
Control group adherence: 70%  
Adverse events: none reported  
24 week follow up measurement  
Measures: 0.12 and 24 weeks  
FIQ measurement  
FIQ  
Patient global assessment (PGA)  
Physical global assessment  
PSQI  
6 min walk test  
BMI  
SF-36 Health Survey  
Comments: Only study complementary alternative medicine (CAM) or exercise trial in fibromyalgia to be published in the New England Journal of Medicine to date.

Taggart, Arslanian, Bae and Singh (2003)  
Open label  
Yang style short form tai chi  
1 hour tai chi classes twice weekly for 6 weeks  
\( n = 37 \)  
Mean age: 56.2  
(35 women and 2 men)  
2 withdrew; 2 couldn’t do exercises; 1 had back surgery; 9 had incomplete data sheets  
Adverse events: none reported  
None  
SF-36 Health Survey  
Baseline only: Wellbeing health history questionnaire  
Comments: Meta analysis is based on pain not total FIQ; 1st attempt at tai chi study in fibromyalgia.

Other CAM exercise studies

Altan, Korkmaz, Bingol and Gunay (2009)  
RCT  
Pilates  
1 hour pilates program 3 times weekly for 12 weeks following basic principles of Pilates method and using resistance bands and 26 cm pilates ball  
Control group usual care = home exercise relaxation/stretching program  
\( n = 50 \)  
Mean age: 49.16 years  
Total completion rate: 98%  
Intervention completion rate: 100%  
Adverse events: none reported  
Week 24 follow up measurement  
Baseline, 12 and 24 weeks  
Pain-visual analog scale  
FIQ  
Tender point count- using standard pressure algometer  
Algometric score  
Lower extremity endurance-chair test  
SF-36 Health Survey  
Nottingham Health Profile (NHP)  
Comments: Only study to look at pilates; merits further investigation due to positive findings and pilates emphasis on core muscles that articulate with the spine potential decreasing spine pain in fibromyalgia.

Maddali-Bongi, Di Felice, Del Rosso, Landi, Maresca, Gianbalvo Dal Ben and Matucci-Cerinic  
Pilot open study  
Body movement and perception  
method following resseguier method  
Twice weekly 50 minute sessions for 8 weeks  
4 groups of 10 people each  
\( n = 40 \) women  
Mean age: 51.7 years  
Completion rate: 100%  
Adverse events: none reported  
No follow up  
Visual Analog Scale (VAS)  
Pain intensity  
Pain temporal characteristics  
Pain during work activities  
Pain during recreational activities  
Interference of pain in night time rest  
General conditions (tiredness, irritability, well-being)  
Movement quality (Stiffness, agility)  
Subjective availability to focus on perception  
Ability to perceive the whole body  
Perceived postural self-control  
Ability to relax mind and body  
Comments: Outcome measure pain intensity versus FIQ total; least physically active of all trials reviewed; may be a niche for those unwilling to do vigorous exercise.

(Continued)
**Table 1 (Continued)**

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<tr>
<th>Author</th>
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<tbody>
<tr>
<td>Carbonell-Baeza, Aparicio, Martins-Pereira, Gatto-Cardia, Ortega, Huertas, Tercedor, Ruiz, and Douglas-Fernandez (2010)</td>
<td>Non-random clinical trial with wait list replication</td>
<td>Biodanza 120 minute weekly sessions divided into 2 phases: Verbal (education/sharing) 35–45 minutes Vivencia (living experience) moving and dancing 75–80 minutes</td>
<td>255 invited, 79 eligible, 7 did not meet inclusion criteria n = 71 Total completion rate = 83.1% Intervention completion rate = 72.97% Control completion rate = 94.12% Adverse events = none reported</td>
<td>No follow-up</td>
<td>Pre and post assessment Tender points Body composition Physical fitness (functional senior fitness test battery) Lower body muscle strength (30 second chair stand test) Upper body muscle strength (handgrip strength) Lower body flexibility (chair sit and reach test) Upper body flexibility (back scratch test) Static balance (blind flamingo test) Aerobic endurance (6 min walk test) FIQ Short form health survey (health r/t QOL) HADS VPMI RSES General self-efficacy scale</td>
</tr>
</tbody>
</table>

Comments: Another example of didactic and movement component combined; unique dance style intervention; comprehensive outcome measures.

**Abbreviations:** BARS, Body Awareness Rating Scale; BDI, Beck Depression Inventory; BMI, Body Mass Index; BPI, Brief Pain Inventory; CAM, Complementary Alternative Medicine; CFQ, chaoyi fanhaun qigong; CPAQ, Chronic Pain Acceptance Questionnaire; FFMQ, Five Facet Mindfulness Questionnaire; FIQ, Fibromyalgia Impact Questionnaire; FIQR, Fibromyalgia Impact Questionnaire Revised; HADS, Hospital Anxiety and Depression Scale; MFI-20, Multidimensional Fatigue Inventory; NHP, Nottingham Health Profile; NRS, Numeric Rating Scale; PCS, Pain Catastrophizing Scale; PDI, Pain Disability Index; PGA, Patient Global Assessment; PI, Primary Investigator; PSQI, Pittsburgh Sleep Quality Index; QOL, Short form health survey; RCT, Randomized Controlled Trial; RSES, Rosenberg Self-Esteem Scale; SF-36, Short Form-36; SF-MPQ, Short Form McGill Pain Questionnaire; SLAP, Sum of Local Areas of Pain; STAI, State Anxiety Inventory; STORK, Static balance-timed single leg stance; TUG, Timed Up and Go; VAS, Visual Analog Scale; VNS, Visual Numerological Scale; VPMI, Vanderbilt Pain Management Inventory; WHO, World Health Organization; WHOQOL-BREF, WHO Quality of Life BREF.
<table>
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<th>Study name</th>
<th>Comparison</th>
<th>Std diff in means</th>
<th>Standard error</th>
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<th>Upper limit</th>
<th>Z-value</th>
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<td>Pilanes</td>
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**Figure 2** Qigong forest plot. Abbreviations: std diff, standard difference; CI, confidence interval.

**Figure 3** Tai chi forest plot. Abbreviations: std diff, standard difference; CI, confidence interval.

**Figure 4** Yoga forest plot. Abbreviations: std diff, standard difference; CI, confidence interval.

**Figure 5** Other CAM forest plot. Abbreviations: BMP, body movement and perception therapy; CAM, complementary and alternative medicine; std diff, standard difference; CI, confidence interval.
Most studies reported both pre- and posttreatment scores, with a number reporting longer-term follow-ups. For the purpose of the current analysis, only pre- and post-effects were assessed. There were no significant differences among the baseline means and standard deviations across the studies.

**Meta-analyses**

The standard difference in means (0.84), and standard errors (0.07) for CAM exercise, indicates a statistically significant ($P = 0.00$) and positive outcome. The individual forest plots for qigong, tai chi, yoga, and all others are reported in Figures 2–5 respectively. With the exception of two studies, all studies reported positive outcomes. Of those not reporting positive outcomes, Mannerkorpi and Arndorfer found no difference between 14 weeks of qigong versus a sedentary “usual care” control in 36 FM patients. Likewise, Carbonell-Baeza et al concluded that a 4-month male tai chi study ($n = 6$) was negative for symptom improvement.

**Sensitivity analyses**

A funnel plot of the Std diff in means indicates that if the standard difference in means (0.84) is true, there is little evidence for reporting bias. The majority of studies fell within two standard deviations, with an equal number of studies falling outside this on either side of the plot (Figure 6). A regression of the Jadad scores on the standard difference of means indicates more variation reported in the lower scores and less in the higher scores, with a slight increase in the slope seen with higher scores (Figure 7).

**Validity analysis**

There was a significant amount of heterogeneity in the studies presented in this analysis. This can be seen in the means and

---

Figure 6 Funnel plot of standard error by standard difference in means. Abbreviation: std diff, standard difference.

Figure 7 Regression of Jadad score on standard difference in means (Jadad et al, 1996). Abbreviation: std diff, standard difference.
confidence intervals in the subplots. The distributions of the forest plots suggest that the results are randomly distributed, indicating that the results are mostly consistent within each type of exercise.

Discussion
The data presented support the likely safety of CAM exercise interventions, as 832 participants were enrolled in 16 studies and 81% completed the studies without differential attrition by study arm or exercise modality.\textsuperscript{58-77} Only one study reported negative side effects (increased shoulder pain and plantar fasciitis) in two study participants.\textsuperscript{70} All studies reported that there were no serious adverse events.

The data also support some degree of efficacy of several of the CAM exercise interventions in improving overall FM symptoms and physical function. Taken as a whole, the data do not indicate that any one intervention type is consistently superior to another, though the strongest effects were for the exercise modalities with the largest number of trials: qigong (Std diff in means 0.47; \(P < 0.000\)) and tai chi (Std diff in means 1.14; \(P < 0.000\)). Further support for qigong comes from a trial excluded from this analysis. Stephens et al\textsuperscript{70} randomized 30 children (ages 8–18) with FM to aerobics or qigong. There was no difference between study arms, although qigong was intended to be the control group. The qigong group did demonstrate significant within-group changes, indicating that pediatric CAM exercise interventions may be a promising area of research. This is critical, as few interventions address pediatric FM even though its recognition as a valid diagnosis is increasing. This may indicate that mind–body exercises may be a feasible therapeutic option across a wider range of developmental states.\textsuperscript{76-80}

Complete data were only available for three yoga trials (two were open labeled) but were positive (Std diff in means 0.45; \(P < 0.015\)).\textsuperscript{52,64,67} Additional support for the benefit of yoga is found in two studies that are not represented in the analyses due to missing data. da Silva et al\textsuperscript{65} randomized 40 women with FM into an individually delivered intervention of “relaxing” yoga with or without additional tui na (massage). Both groups experienced clinically and statistically significant reductions in FIQ total scores, but there was no difference between treatment arms. Another trial (n = 10) noted a 28% improvement in FIQ total scores following eight weeks of gentle Hatha yoga.\textsuperscript{81} Three other CAM-based exercise studies were positive, but the interventions have yet to be replicated (pilates, Biodanza, and Resseguier with body movement and perception).\textsuperscript{58,60,72} Pilates is a series of nonimpact strength, flexibility, and breathing exercises designed by Joseph Pilates to promote inner awareness and core stability. Biodanza, literally “life-dance,” is a program of exercise that seeks to optimize self-development and deepen self-awareness. It most often uses dance, music, singing, and other movements to promote positive feelings, emotional expression, and connection to others and to nature. Resseguier is based on selected soft, low-impact gymnastic movements integrated with postural self-control, body alignment, and relaxation.

The data are consistent with an earlier rigorous report on “mindful” meditative movement therapies that concluded that these therapies were safe and effective for reducing sleep disturbances, fatigue, and depression, and improving quality of life. In subanalyses, the authors found that only yoga also relieved pain.\textsuperscript{50} However, that meta-analysis was comprised of only RCTs (n = 7). The current data extend these findings by demonstrating efficacy in a combination of FM symptoms and physical function, in a larger number of studies (n = 16).

This meta-analysis shows that research in the area was at an early state (six open-labeled studies), although regressing by Jadad score showed that there was a nonsignificant difference by effect size. This may indicate that early-stage studies are not likely to overreport effect.

This study does have limitations, the greatest being that six of the studies were open labeled. Others may argue, however, that open-labeled trials are appropriate in early-phase research when safety, feasibility, and effect sizes are being determined.\textsuperscript{82} Further, because open-labeled studies were included, community-based exercise studios and instructors were tested, leading the field toward effectiveness rather than efficacy outcomes. The studies were generally small (average n = 51.5; range 6 to 128 participants), limiting their power and the ability to test multiple comparisons or to profile responders’ reliability.

Another limitation is that the studies were largely conducted in middle-aged women, in America and Europe. This is important, as many CAM exercise studies have been conducted in India and China, where many of these traditions are rooted (however, those studies were not available in English or from major database sources). Moreover, differential effects may be found in men, minorities, children and elders. Another limitation is that all the trials employed a single interventionist and did not rate treatment expectancy. It is possible, therefore, that a charismatic or caring instructor, rather than the intervention itself, may have been responsible for the beneficial outcome, although this is less likely in the
trials that have been replicated (qigong, tai chi, and yoga). Future effectiveness studies could use multiple instructors.

A goal of future studies should include the standardization of exercise protocols, including scripting for mindfulness, posture sequences, and a range of modifications based on the patient’s physical ability. To date, studies have varied considerably in exercise dose and have not always provided adequate description of the intervention to allow replication. Publishing protocols in peer-reviewed journals would provide opportunities for a more detailed description of the actual intervention and for pictures of the less common poses or physical strategies. This is important because people with FM are likely to be in poor physical condition, have joint hypermobility, and poor balance, and may be at an increased risk for injury.42

Future studies should incorporate validated scales such as the revised FIQ (FIQ-R), Brief Pain Inventory, Multi-dimensional Fatigue Inventory, Medical Outcomes Study Sleep Scale, and Multiple Ability Self-Report Questionnaire.83,84 Full reporting of data and statistical tests will allow for more seamless comparison in future trials. Some FM exercise studies now report the number needed to treat, based on Patients’ Global Impression of change (PGIC) scale, which allows for direct comparison with pharmaceutical trials.85 Similarly, work is underway to develop a responder index.86

In conclusion, the CAM-based exercise therapies reviewed are likely safe, and no serious adverse events were reported in any study. These exercise programs were somewhat efficacious for FM pain, with many studies reporting improvement in overall FM symptoms and physical function. However, the majority of studies had lower methodological quality. There is a need for large, rigorous trials with active parallel arms—such as traditional aerobic exercise compared with CAM-based exercise—to extend this body of evidence.

Disclosure
The authors report no conflicts of interest in this work.

References


